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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,057	07/23/2003	Edward N. Hill	8789-16CT2	3292

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EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,057	HILL ET AL.	
	Examiner	Art Unit	
	Barbara P. Badio, Ph.D.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-7,10,13-18,21,24-29 and 33-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-7,10,13-18,21,24-29 and 33-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

First Office Action on the Merits

Specification

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 4-7, 10, 13-18, 21, 24-29 and 32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,844,334. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass similar 1,3,5(10),6,8-pentaen-estradiol derivatives. The difference between the two is based on the scope of the claimed compounds. Unlike, the present application, the above-mentioned patent is limited to specific salts of compounds disclosed in the

present application (see compounds of formulae II and III, sections 0069-0072 of the present specification). The skilled artisan in the art would be motivated to make any of the compounds of the genus recited by the instant claims, including those recited by U.S. Patent No. 6,844,334, because said salts are disclosed by the present specification (see section 0072). Thus, the skilled artisan would have the reasonable expectation that the any of the compounds of the claimed genus, including salts thereof, would have the desire activity as disclosed by present specification and the disclosure of the cited patent.

4. Claims 1, 4-7, 10, 13-18, 21, 24-29 and 32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,660,726. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass similar 1,3,5(10),6,8-pentaen-estradiol derivatives. The difference between the two is based on the scope of the claimed compounds. Unlike, the present application, the above-mentioned patent is limited to the 3-sulfate of compounds disclosed in the present application (see compounds of formulae II and III, sections 0069-0072 of the present specification). The skilled artisan in the art would be motivated to make any of the compounds of the genus recited by the instant claims, including those recited by U.S. Patent No. 6,660,726, because said sulfate derivative and salts thereof are disclosed by the present specification (see section 0071-0072). Thus, the skilled artisan would have the reasonable expectation that the any of the compounds of the claimed

genus, including salts thereof, would have the desire activity as disclosed by present specification and the disclosure of the cited patent.

5. Claims 10, 13-18, 21, 24-29 and 32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,855,703. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass similar 1,3,5(10),6,8-pentaen-estradiol derivatives, such as 6-OH dihydroequilenin and 6-OH equilenin and sulfate salts thereof. The difference between the two is based on the scope of the claimed composition. Unlike, the present application, the above-mentioned patent recites addition estrogenic compounds not exemplified/disclosed by the present application. However, the claimed composition incorporates other estrogenic compounds such as those recited by the above-mentioned patent (see for example, claims 17, 18, 28 and 29 of the present specification). The skilled artisan in the art would be motivated to make any composition as recited by the instant claims including additional estrogenic compounds as recited by U.S. Patent No. 6,855,703 because the skilled artisan would have the reasonable expectation that said composition would have the desire activity as disclosed by present specification and the disclosure of the cited patent.

6. Claims 35 and 36 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 33 and 34, respectively. When two claims in an application are

duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 18, 29 and 33-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 18 and 29 recite "vitamin D and its derivatives". However, the only example of vitamin D disclosed by the present specification is calcitriol. Therefore, the present specification lacks description of what is intended and, thus, encompassed by the term "derivatives" as recited by the instant claims.

Claims 33-36 recite compounds not described/disclosed by the present specification. In other words, the present specification does not convey to the skilled artisan in the art that applicant(s), at the time the application was filed, had possession of the claimed invention.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1, 4-7, 10, 13-18, 21, 24-29 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of the instant claims is confusing for the following reasons:

(a) It is unclear how any of one of R_4-R_7 and R_{10}-R_{13} can represent "ketone" when the other substituent at the same position represents another atom such as hydrogen;

(b) Claims 18 and 29 recite "vitamin D and its derivatives" however, the present specification lacks description of what a "derivative" of vitamin D is. Thus, the skilled artisan in the art would be unable to determine the metes and bound of the claimed invention; and

(c) Claims 6, 15 and 26 recite "the compound has a β orientation". It is not clear how a compound can have a β orientation. It is recognized in the chemical art that a substituent of a compound can be in the α- or β- orientation as disclosed by the present specification (see section 0067 of the present specification). However, the art does not recognize a compound having an alpha or beta orientation.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 4-7, 10, 13-16, 21 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Harnik (IL 25265).

Harnik teaches several estrogenic estrane derivatives such as 3,6-dimethoxy-estra-1,3,5,7,9-pentaen-17-ol and 3,6-dimethoxy-estra-1,3,5,7,9-pentaen-17-one (see Abstract). The compounds and compositions taught by the reference are encompassed by the instant claims.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 17, 18, 28, 29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harnik (IL 25265).

Harnik teaches several estrogenic estrane derivatives such as 3,6-dimethoxy-estra-1,3,5,7,9-pentaen-17-ol and 3,6-dimethoxy-estra-1,3,5,7,9-pentaen-17-one (see Abstract).

The instant claims differ from the reference by reciting the addition of other pharmaceutically active ingredient(s) such estrogenic compounds. However, the combination of two or more compounds/compositions having the same use to form a third having the same use is prima facie obvious. Thus, it would have been obvious to the skilled artisan in the art to combine another estrogenic compound with the compounds of Harnik with the reasonable expectation that the combination would maintain its estrogenic property and, thus, be useful in treatment of hypo estrogenic conditions known in the art such as those associated with menopause.

Telephone Inquiry

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
February 18, 2005